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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/635,928	VENKATARAMAN, BALAJI	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-12,15-19,22-31 and 33-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-12, 15-19, 22-31, 33-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The following office action is a responsive to the Amendment filed, 12/07/07.

The amendment filed 12/07/07 affects the application, 10/635,928 as follows:

Claims 15, 24, 41-44 have been amended. Applicant's amendment has overcome the 102 rejections of the prior office action mailed 09/07/07. The arguments have overcome the rejections of the Composition Claims Under 35 U.S.C. § 103. However, a new ground (s) of rejections is set forth herein.

The responsive to applicants' amendment is contained herein below.

Claims 1-5, 7-12, 15-19, 22-31, 33-45 are pending in application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-12, 23, 25-29, 31, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (Molecular Genetics and Metabolism, **67**, 43-48 (1999) in combination with Ravn et al. (European Journal of Obstetrics, Gynecology, and Reproductive Biology, (1994 Feb) Vol. 53, No. 2, pp. 81-93, Abstract Only).

In claim 1, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1,

are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6, and specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 23 is drawn to composition consisting of calcium, vitamin D, folic acid, hydroxycobalamin (vitamin B12) and vitamin B6. Dependent claims 25-29 are drawn to specific amounts of hydroxocobalamin (vitamin B12) and folic acid.

Brown et al. disclose that supplementation of with folic acid, vitamin B_6 and vitamin B_{12} as well as posmenopausal Hormone Replacement Therapy (HRT) has shown to reduce plasma homocysteine levels significantly and that elevated homocysteine is an independent risk factor for cardiovascular disease (see page 47, left col., last two paragraphs and abstract). Furthermore, Brown et al. disclose that the risk of coronary artery disease (a cardiovascular disease) increases with rising homocysteine levels (see page 47, left col., last two paragraphs). In addition, Brown et al. disclose that the use of postmenopausal hormones has many benefits, including a decreased risk of osteoporosis and cardiovascular disease (which includes coronary heart disease) (see page 47, left col., last two paragraphs).

The difference between applicant's claimed composition and the dietary supplement (composition) disclosed by Brown et al. is that applicant's composition also contains calcium and vitamin D.

Ravn et al. disclose that women (i.e., posmenopausal women) at risk of osteoporosis will benefit from Hormone Replacement Therapy (HRT) (see abstract). Furthermore, Ravn et al. disclose that the treatment may be supplemented with extra calcium and vitamin D and maybe calcitnonin (see abstract). Furthermore, Ravn et al. disclose that women at risk of cardiovascular disease will also benefit from Hormone Replacement Therapy (HRT) and that there is

overwhelming evidence that hormonal therapy will protect against both coronary heart disease and stroke, and there is no increase risk of venous thrombosis or hypertension (see abstract). Also, Ravn et al. suggest that every woman showing signs of hormonal deprivation should be treated with Hormone Replacement Therapy (HRT) and that said women includes women at risk of osteoporosis (fast bone losers) and cardiovascular diseases (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Brown et al. and Ravn et al. to prepare a supplement or composition such as a dietary supplement consisting of folic acid, vitamin B12, vitamin B6 calcium and vitamin D to be administered to postmenopausal women undergoing Hormone Replacement Therapy (HRT) in order to treat, prevent or decrease the risk of osteoporosis and cardiovascular disease in said postmenopausal women, since Brown et al. and Ravn et al. compositions are disclosed as having the same utility and since the combination of compounds that are used to treat the same condition or diseases are well known in the art.

It is generally considered prima facie obvious to combine active agents each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional, and required, nutritional agents. It would follow that the recited claims define prima facie obvious subject matter. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been in view of Brown et al. and Ravn et al. to prepare a supplement or composition such as a dietary supplement consisting of folic acid,

vitamin B12, vitamin B6 calcium and vitamin D to be administered to postmenopausal women undergoing Hormone Replacement Therapy (HRT) in order to treat, prevent or decrease the risk of osteoporosis and cardiovascular disease in said postmenopausal women, because a skilled artisan would reasonably be expected to use the composition taught by Brown et al. in combination with calcium and vitamin D composition taught by Ravn et al. to treat said condition or disease based on need, like the severity of the condition or disease and the type of postmenopausal woman that is being treated. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factors like the severity of the condition and the mass or age of the postmenopausal women being treated. In particular, all specific amounts claimed herein are within the well-known ranges of effective amounts of agents to be administered. Note that the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Further, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. and Ravn et al. as applied to claim 1 above, and further in view of Bell et al. (WO 99/65337).

In claim 35, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin C." In claim 36, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and iron." In claim 37, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6, vitamin C and iron." Dependent claims 38-40 are drawn to said composition wherein vitamins B12 is hydroxocobalamin.

The difference between applicant's claimed composition and the composition taught by Brown et al. and Ravn et al. is that the applicant composition also contains vitamins and/or minerals.

Bell et al. disclose that calcium intake certain vitamins and minerals enhance calcium absorption and utilization and that adequate calcium intake limits the development of osteoporosis (see page 1, 22-24). Furthermore, Bell et al. disclose that dietary supplements can also contain vitamins and mineral which includes those claimed by applicant (see page 10, lines 21 to 36).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Brown et al., Ravn et al. and Bell et al., to prepare a composition consisting of a combination of a calcium, vitamin D, folic acid, vitamin B12, vitamin B6, and a vitamin such as vitamin C or a mineral such as iron, to be administered to postmenopausal women undergoing Hormone Replacement Therapy (HRT) in order to decrease the risk of osteoporosis and cardiovascular disease in said postmenopausal women, since Brown et al. and

Ravn et al. compositions are disclosed as having the same utility and Bell et al. disclose that calcium intake certain vitamins and minerals enhance calcium absorption and utilization and that adequate calcium intake limits the development of osteoporosis and suggest that dietary supplements can also contain vitamins and mineral (which includes those claimed by applicant).

One having ordinary skill in the art would have been motivated in view of Brown et al., Ravn et al. and Bell et al., to prepare a composition consisting of a combination of a calcium, vitamin D, folic acid, vitamin B12, vitamin B6, and a vitamin such as vitamin C or a mineral such as iron, to be administered to postmenopausal women undergoing Hormone Replacement Therapy (HRT) in order to treat, prevent or decrease the risk of osteoporosis in said postmenopausal women, because a skilled artisan would reasonably be expected to use the composition taught by Brown et al., Ravn et al. and Bell et al. to treat said condition or disease based on need, like the severity of the condition or disease and the type of postmenopausal woman that is being treated. It should be noted that claims 38-40 which are drawn to specific kinds of vitamins B12 (i.e. hydroxocobalamin) are also encompassed by the aforementioned rejection since the type of vitamin B12 used in the composition depends on factor like the severity of the condition and the mass or age of the postmenopausal women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

It is generally considered prima facie obvious to combine active agents each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their

having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional, and required, nutritional agents. lt would follow that the recited claims define prima facie obvious subject matter. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Note that the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Claims 15-19, 22, 24, 30, 33, 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (Molecular Genetics and Metabolism, **67**, 43-48 (1999) in combination with Ravn et al. (European Journal of Obstetrics, Gynecology, and Reproductive Biology, (1994 Feb) Vol. 53, No. 2, pp. 81-93, Abstract Only).

In claim 15, applicant claims "A method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in an individual consisting essentially of comprising administering to the individual an effective amount of a composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 16-19, 22 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 24 is drawn to a method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in an individual consisting essentially of administering to the individual an effective amount of a vitamin composition consisting of calcium, vitamin D, folic acid, hydroxocobalamin and vitamin B6. Claims 30, 33 are drawn to

said method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss using specific amounts or quantities of the components in the composition. Claims 44-45 are drawn to a method of administering to a menopausal woman an effective amount of said composition effective to treat hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone in said menopausal woman, and specific cause of said treated condition.

Brown et al. disclose that supplementation of with folic acid, vitamin B_6 and vitamin B_{12} as well as posmenopausal Hormone Replacement Therapy (HRT) has shown to reduce plasma homocysteine levels significantly and that elevated homocysteine is an independent risk factor for cardiovascular disease (see page 47, left col., last two paragraphs and abstract). Furthermore, Brown et al. disclose that the risk of coronary artery disease (a cardiovascular disease) increases with rising homocysteine levels (see page 47, left col., last two paragraphs). In addition, Brown et al. disclose that the use of postmenopausal hormones has many benefits, including a decreased risk of osteoporosis and cardiovascular disease (which includes coronary heart disease) (see page 47, left col., last two paragraphs). This suggest that a supplement of folic acid, vitamin B_6 and vitamin B_{12} can be used to treat prevent or decrease the risk of osteoporosis and cardiovascular disease in posmenopausal women undergoing Hormone Replacement Therapy (HRT).

The difference between applicant's claimed method and the method disclosed by Brown et al. is that applicant's composition also contains calcium and vitamin D.

Ravn et al. disclose that women (i.e., posmenopausal women) at risk of osteoporosis will benefit from Hormone Replacement Therapy (HRT) (see abstract). Furthermore, Ravn et al. disclose that the treatment may be supplemented with extra calcium and vitamin D and maybe calcitnonin (see abstract). Furthermore, Ravn et al. disclose that women at risk of cardiovascular

disease will also benefit from Hormone Replacement Therapy (HRT) and that there is overwhelming evidence that hormonal therapy will protect against both coronary heart disease and stroke, and there is no increase risk of venous thrombosis or hypertension (see abstract). Also, Ravn et al. suggest every woman showing signs of hormonal deprivation should be treated with Hormone Replacement Therapy (HRT) and that said women includes women at risk of osteoporosis (fast bone losers) and cardiovascular diseases (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Brown et al. and Ravn et al. to treat, prevent or reduce the risk of osteoporosis and cardiovascular disease in a menopausal woman undergoing Hormone Replacement Therapy (HRT) by administering to said postmenopausal woman a supplement or composition such as a dietary supplement consisting of folic acid, vitamin B12, vitamin B6 calcium and vitamin D in order to treat, prevent or reduce the risk of osteoporosis and cardiovascular disease in said postmenopausal women, since Brown et al. and Ravn et al. compositions are disclosed as having the same utility and since the combination of compounds that are used to treat the same condition or diseases are well known in the art.

It is generally considered prima facie obvious to combine active agents each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional, and required, nutritional agents. It would follow that the recited claims define prima facie obvious subject matter. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been in view of Brown et al. and Ravn et al. to treat, prevent or reduce the risk of osteoporosis and cardiovascular disease in a menopausal woman undergoing Hormone Replacement Therapy (HRT) by administering to said postmenopausal woman a supplement or composition such as a dietary supplement consisting of folic acid, vitamin B12, vitamin B6 calcium and vitamin D in order to treat, prevent or reduce the risk of osteoporosis and cardiovascular disease in said postmenopausal women, because a skilled artisan would reasonably be expected to use the composition taught by Brown et al. in combination with calcium and vitamin D taught by Ravn et al. to treated said condition or disease based on need, like the severity of the condition or disease and the type of postmenopausal woman that is being treated. It should be noted that claims 15-19, 22, 24, 30, 33, 44-45 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the postmenopausal women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. and Ravn et al. as applied to claim 1 above, and further in view of Bell et al. (WO 99/65337).

In claim 41, applicant claims is drawn to method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in an individual consisting essentially of

comprising administering to the individual an effective amount of a composition consisting of an effective amount of a composition of claim 35. Claims 42 and 43 are drawn to method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in an individual consisting essentially of comprising administering to the individual an effective amount of a composition consisting of an effective amount of a composition of claim 36 and 37, respectively.

The difference between applicant's claimed method and the method taught by Brown et al. and Ravn et al. is that the applicant composition also contains vitamins and/or minerals.

Bell et al. disclose that calcium intake certain vitamins and minerals enhance calcium absorption and utilization and that adequate calcium intake limits the development of osteoporosis (see page 1, 22-24). Furthermore, Bell et al. disclose that dietary supplements can also contain vitamins and mineral which includes those claimed by applicant (see page 10, lines 21 to 36).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Brown et al. and Ravn et al. to treat, prevent or reduce the risk of osteoporosis and cardiovascular disease in a menopausal woman undergoing Hormone Replacement Therapy (HRT) by administering to said postmenopausal woman a supplement or composition such as a dietary supplement consisting of folic acid, vitamin B12, vitamin B6 calcium and vitamin D in to treat, prevent or reduce the risk of osteoporosis and cardiovascular disease in said postmenopausal women, since Brown et al. and Ravn et al. compositions are disclosed as having the same utility and Bell et al. disclose that calcium intake certain vitamins and minerals enhance calcium absorption and utilization and that adequate calcium intake limits

the development of osteoporosis and suggest that dietary supplements can also contain vitamins and mineral (which includes those claimed by applicant).

One having ordinary skill in the art would have been in view of Brown et al. and Ravn et al to treat, prevent or reduce the risk of osteoporosis and cardiovascular disease in a menopausal woman undergoing Hormone Replacement Therapy (HRT) by administering to said postmenopausal woman a supplement or composition such as a dietary supplement consisting of folic acid, vitamin B12, vitamin B6 calcium and vitamin D in order to treat, prevent or reduce the risk of osteoporosis and cardiovascular disease in said postmenopausal women, because a skilled artisan would reasonably be expected to use the composition taught by Brown et al., Ravn et al. and Bell et al. to treated said condition or disease based on need, like the severity of the condition or disease, and the type postmenopausal woman that is being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Response to Arguments

Applicant's arguments with respect to claims 1-5, 7-12, 15-19, 22-31, 33-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be

reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

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Supervisory Patent Examiner, Art Unit 1623
January 6, 2008.